In the Supreme Court of the United States

OCTOBER TERM, 1966

No.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS, PETITIONERS

v.

THE TOILET GOODS ASSOCIATION, INC., ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

The Solicitor General, on behalf of the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs, petitions for a writ of certiorari to review the judgment of the court of appeals insofar as it sustains the district court's denial of the petitioners' motion to dismiss the complaint.

OPINIONS BELOW

The opinion of the court of appeals (App. A, *infra*, pp. 1a–22a; II R. 72–93) [1] is reported at 360 F. 2d 677.

[1] "R." designates the two-volume certified record on file in No. 336, this Term, presently pending on petition for certiorari. The record in No. 336 is also the record in this case since the

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The first opinion of the district court (I R. 88–99) is reported at 235 F. Supp. 648; the second (I R. 7–14) is not yet reported.

JURISDICTION

The judgment of the court of appeals was entered on April 13, 1966 (App. B, *infra*, p. 23a; II R. 94). On July 7, 1966, Mr. Justice Stewart extended the time for filing a petition for a writ of certiorari to and including August 11, 1966. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether interpretive regulations issued by the Commissioner of Food and Drugs under the 1960 "Color Additive" Amendments to the Federal Food, Drug and Cosmetic Act may be challenged in an action for declaratory judgment.

STATUTES AND REGULATIONS INVOLVED

The relevant statutes and regulations are set forth in Appendix C, *infra*, pp. 24a–27a.

STATEMENT

In 1960, Congress adopted the "Color Additive Amendments" to the Federal Food, Drug and Cosmetic Act, 74 Stat. 397, 21 U.S.C. 321.[2] Insofar as per-

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two cases arise from the very same proceedings; the cases differ at this stage only to the extent that each seeks review of different aspects of the judgment of the court of appeals.

We are also filing herewith a separately paginated copy of the complaint (herein "C") since a number of pages have been inadvertently omitted from the complaint contained in the certified record in No. 336.

[2] The paramount purpose of the amendments was to substitute the "safety-in-use" test for color additives which could not meet the test of harmlessness per se adopted by this Court in *Fleming* v. *Florida Citrus Exchange*, 358 U.S. 153.

tinent here, the amendments provided that a cosmetic should be deemed adulterated if it is, bears or contains a color additive that has not been listed and certified as safe for its intended use by the Food and Drug Administration (except where administratively exempted from such listing and certification requirements). The amendments also prescribed the general pre-marketing standards and procedures the Food and Drug Administration was to follow for listing and certifying color additives as safe for use and provided that administrative regulations should issue to specify the conditions of safe use, including any needed tolerances or other restrictions applicable to assure safety in use of the color additives. Section 201(t)(1) of the Amendments defined a "color additive" as:

> (A) * * * a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and
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> (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto * * *.

On January 24, 1961, the Commissioner of Food and Drugs, acting pursuant to his delegated authority to adopt regulations for "efficient enforcement" of the Act (21 U.S.C. 371(a)) and under Section 4 of the Administrative Procedure Act, gave public notice of

his intention to promulgate interpretive and procedural regulations for the administration of the "Color Additive" Amendments (26 F.R. 679). After receiving numerous comments from interested parties, including some from the respondents herein, and evaluating available data, such regulations were adopted in final form on June 22, 1963 (28 F.R. 6439; 21 C.F.R. 8.1 *et seq.*; see Appendix C, *infra*, pp. 26a–27a).

In November 1963—five months after the adoption of the regulations—respondents[3] filed a complaint in the United States District Court for the Southern District of New York under the Declaratory Judgment and the Administrative Procedure Acts (see Appendix C, *infra*, pp. 24a–25a), seeking a declaration that four of the regulations constituted an unwarranted expansion of the statutory amendments not contemplated by Congress.

In essence, three of the challenged regulations (21 C.F.R. 8.1 (f), (m) and (u)) interpreted the statutory definition of the term "color additive" to include: (1) all finished cosmetic products intended for coloring the human body (*i.e.*, lipstick, rouge, eye makeup colors and related cosmetics); (2) "all diluents"—non-pigmented materials with which colors are mixed to facilitate their use; and (3) certain hair dyes, the injurious qualities of which could not be ascertained and avoided by a simple preliminary patch test per-

[3] The Toilet Goods Association ("Toilet Goods") is a trade association of cosmetic manufacturers whose members allegedly sell in excess of 90% of the annual sales of cosmetics in the United States. The forty other respondents are manufacturers and distributors of cosmetic products (I R. 18–19).

formed by the purchaser, and which were thus, according to the administrative interpretation, not within the statutory "hair dye" exemption in Section 601(a) of the Act. The fourth regulation provided that the Food and Drug Commissioner "may immediately suspend certification service" when the manufacturer has "[r]efused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived" (21 C.F.R. 8.28(a)(4)).

After asserting that Congress did not intend that a finished cosmetic product be treated as a color additive subject to pre-marketing testing and clearance requirements (C. 6–14),[4] the complaint alleged that the regulations threatened immediate and irreparable injury to respondents in that they either had to meet the listing and certification requirement at great financial expense, disruption of long-settled business practices, curtailment of a new product distribution, and disclosure of secret formulae and processes, or else face civil or criminal suits for non-compliance, the very institution of which would seriously injure consumer confidence in their products (C. 14–17, 19–20; 23, 25–26). Petitioners moved to dismiss asserting, *inter alia*, that the regulations were fully consonant with the Congressional purpose of insuring consumer safety in the use of "color additives" including color-

[4] The particularized allegations challenging the validity of the regulations are summarized in the opinion of the court of appeals (App. A, *infra*, pp. 7–8).

imparting cosmetics (I R. 374–376), and that respondents were required first to exhaust their administrative remedy by providing proof of safety for use and seeking judicial review of an adverse determination if the administrative order did not permit the marketing of products which respondents considered permissible under the statute. Petitioners contended further that the regulations had no immediate impact since their application in a specific instance had not been called into operation (I R. 86).

The district court denied the motion to dismiss, finding that the complaint did set forth a justiciable controversy as to each of the challenged regulations (I R. 99).[5] The court, however, denied respondent's motion for summary judgment and set the case down for trial. It stated that while the questions for resolution were essentially matters of statutory interpretation, expert testimony would be adduced at the trial with respect to "the technical problems involved" and "since professionally qualified representatives of both plaintiffs and defendants were present during the hearings and debates which preceded the passage of the 1960 Color Additive Amendments, it would be

[5] In so holding, the court relied in major part on the decision in *Abbott Laboratories* v. *Celebrezze*, 228 F. Supp. 855 (D. Del.), where a declaratory judgment had been granted invalidating an interpretive drug-labeling regulation as exceeding the authority granted by Congress under the 1962 Drug Amendments of the Federal Food, Drug and Cosmetic Act (I R. 88–96). That decision was reversed by the Court of Appeals for the Third Circuit on the ground that the issue was not justiciable. 352 F. 2d 286. Certiorari has been granted in that case, 383 U.S. 924, No. 39, this Term.

helpful to hear their testimony relative to legislative intent, which presumably, they had an important role in shaping and assisting" (I R. 98, 96).

About a year later (after pre-trial discovery proceedings) the district court allowed petitioners to renew their motion to dismiss and for summary judgment (I R. 100–101). These motions requested the court to reconsider its ruling on the question of justiciability in light of the Third Circuit's decision in *Abbott Laboratories* v. *Celebrezze*, 352 F. 2d 524 (I R. 102–106), reversing the district court's holding in that case (*supra*, n. 5, p. 6), that the validity of an administrative regulation interpreting a 1962 Drug Amendment to the Federal Food, Drug and Cosmetic Act was justiciable. The Third Circuit had found the regulation not to be subject to judicial review by way of declaratory judgment (a) because the court found in the statutory scheme an intent to preclude judicial review at that juncture of the validity of that kind of regulation, and (b) because absent any agency attempt at enforcement of the regulation there was not posed the "actual controversy" required to justify relief under the Declaratory Judgment Act. After argument, the district court in this case adhered to its earlier decision (I R. 7–13).

On an interlocutory appeal under 28 U.S.C. 1292 (b) (II R. 68), the court of appeals affirmed in part and reversed in part.[6] With respect to the three regulations interpreting the statute as requiring that

[6] While the case was pending before it, this Court granted certiorari in *Abbott Laboratories*, No. 39, this Term.

finished cosmetics, all diluents and certain hair dyes be subject to pre-marketing listing and certification, the court held their validity raised issues of statutory construction ripe for judicial resolution. In so ruling, the court specifically rejected the argument that judicial review procedures provided by the "Color Additive" Amendments were meant to be exclusive and noted that the Third Circuit's decision in *Abbott Laboratories* could not be satisfactorily distinguished. The court did suggest, however, that if, during trial, it turned out that there was need for detailed factual evidence best produced at agency hearings, or that the agency had reduced the hardships of proceeding to review through the statutory process, the district court could refuse to enter a declaratory judgment (I R. 83–91).

As for the regulation relating to agency inspection of formulae and processes, the court found judicial intervention premature since the regulation was cast in tentative terms, no administrative action had been taken under it and, at this stage, it appeared that adequate relief was provided by a companion regulation (21 C.F.R. 8.28(b)) (II R. 91–93).

REASONS FOR GRANTING THE WRIT

The court below recognized that its views conflicted squarely with those of the Court of Appeals for the Third Circuit in *Abbott Laboratories* v. *Celebrezze*, 352 F. 2d 286, in which certiorari has been granted by this Court, 383 U.S. 924, No. 39, this Term. The "ripeness" and "justiciability" issues in *Abbott Laboratories* and in the instant case are similar, and this Court's decision in *Abbott Laboratories* may control the question whether the judgment of the court of ap-

peals in this case should be disturbed. Consequently, it might be appropriate in ordinary circumstances for this Court to defer action on this petition and on the petition in No. 336 until after its decision in *Abbott Laboratories*.

On the other hand, this case involves different regulations from those involved in *Abbott Laboratories*, and a different statutory scheme for judicial review. We therefore believe it would be helpful to the Court to consider the issues presented against the background of various kinds of regulations issued under the Food, Drug and Cosmetic Act. That could be achieved if this petition and the petition in No. 336 were granted and set for argument together with No. 39.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that this petition for a writ of certiorari be granted and the case be set down for argument together with *Abbott Laboratories* v. *Gardner*, No. 39, this Term and with the respondents' petition in this case, No. 336, this Term.

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